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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,293	08/26/2003	Christopher T. Maus	4L01.1-064	5478
35725 7590 06/14/2007 MEHRMAN LAW OFFICE, P.C. ONE PREMIER PLAZA			EXAMINER SIEFKE, SAMUEL P	
, 0.			1743	
,				
			MAIL DATE	DELIVERY MODE
			06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/649,293	MAUS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Samuel P. Siefke	1743				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period we failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. nely filed the mailing date of this communication.  D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
· — · · · · · · · · · · · · · · · · · ·	action is non-final.					
<u></u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E		•				
Disposition of Claims						
4)⊠ Claim(s) <u>26-33</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>26-31</u> is/are rejected.						
7)⊠ Claim(s) <u>32 and 33</u> is/are objected to.		•				
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers	·					
9)☐ The specification is objected to by the Examiner	-					
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	•					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119		Action of 101111 1 0°102.				
<u>-</u>						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
-		•				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary	•				
2) Motice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal Pa					
Paper No(s)/Mail Date	6) Other:	. ,				

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (USPN 5,307,263).

Brown discloses a modular based microprocessor-based health monitoring system that comprises: a glucose monitor that comprises a test strip reader for reading a test strip carrying a sample of biological fluid (fig. 1, ref. 16; col. 7, lines 38-39; col. 17, lines 52-60) and obtaining test results based on the sample or biological fluid and calibration data specific to the test strip (col. 17, lines 9-51); a memory reading device (12) functionally connected (14; col. 7, lines 30-37) to the test strip reader and operable for reading the calibration data from a memory device (col. 17, lines 9-51); a data drive (10) functionally connected (18 to the test strip reader and operable for writing the test results to a memory storage device (EEPROM 94; col. 15, line 65-col. 17, line 8).

Brown states that the blood glucose monitor 16 being connected to the data management unit 10 by cable 18 but states that it may be preferable to construct the blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Then goes on to state regardless of the

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manner in which the blood glucose monitor 16 is interconnected with the data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices (col. 7, lines 38-47). Brown discloses a health report server (54) operable for: receiving the test results and additional diagnostic information (col. 11, lines 18-40; col. 11, line 65- col. 12, line 15); compiling a health report based on the test results and the additional diagnostic information (col. 12, line 65-co. 13, line 15; col. 15, lines 19-44); and transmitting the heath report (col. 12, lines 16-28). Brown further discloses a computer station operable (62) for reading the test results from the memory storage device, establishing a network connection with the health report server, receiving the additional diagnostic information, transmitting the test results and the diagnostic information to the health report server, receiving the health report from the health report server and printing the health report (col. 12, lines 29-col. 13, line 46; col. 13, line 60-col. 14, line 8). Regarding claim 2, Brown discloses program instructions stored in data management unit 10 and program instruction stored in program cartridge 42 of handheld microprocessor unit 12 to enable the system to display statistical and trend information either in graphic or alphanumeric format (col. 18, lines 43-47) an also allow trend information to be reported in the health report (col. 11, lines 30-35; col. 19).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (USPN 5,307,263) in view of Levin et al. (USPN 5,724,580).

Brown teaches a modular based microprocessor-based health monitoring system as seen above.

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Brown does not teach measuring blood lipid levels; additional diagnostic information including: a medical risk index, a recommended weight loss, a five year risk of heart attack, a ten year risk of heart attack, a cardiac age, an extended age a risk of stroke; the health report including a data sheet for newly prescribed drugs and the other currently prescribed drugs; a target weight, a schedule for future testing, a health assessment summary, a coronary risk assessment, a dietary guidelines to lower cholesterol.

Levin teaches a system of generating prognosis and therapy reports for coronary health management that comprises inputting parameters of a user into a hand-held monitor that includes general information such as doctors ID number, patient's assigned ID number, birth date, sex, height, weight, coronary status, blood pressure, known allergic conditions, cholesterol levels, glucose levels, present drug regimens, smoking habits and exercise regimes (col. 5, lines 1-9). This information is then transferred to a processing server which computes by algorithm and interprets the history of the patient and proceeds to issue a course of action and treatment (col. 5, lines 26-37). The patient report is printed as seen in figure 25a and 25b which includes a medical risk category, in this example the patient is in the highest risk category for a cardiac event in the next year. The report breaks down, lipid profile, antihypertensive thereapy, antithrombotic therapy, diabetes, smoking cessation, ideal body weight, program of regular exercise, etc where each therapy describes in depth the patients habits or the addition of a newly prescribed drug and other currently prescribed drugs. Regarding claim 28, it would have been obvious to one having an ordinary skill in the art at the time

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of the invention to modify Brown to employ a blood lipid level along with the glucose levels because this provides more knowledge a physician needs to diagnose a patients problems. This further provides the information necessary to perform other tests such as diagnosing hypolipidemic therapy. Further it would have been obvious to modify Brown to include essential patient information such as gender, sex, height, age, weight, blood pressure because these are essential vital information used to make up a heath report of a patient. Regarding claim 29, it would have been obvious to one having an ordinary skill in that art to modify Brown to employ a diagnostic result that included a medical risk index which puts a patient in a risk category because this raises patient awareness of a problem and therefore increase the chances that a patient will take an action to prevent the future problem diagnosed by the physician. Regarding claim 30, it would have been obvious to one having an ordinary skill in the art to modify Brown to employ a diagnostic information relating to newly prescribed drug and other currently prescribed drugs and if there are any cross-reaction between the newly prescribed drug and the currently prescribed drug because this would prevent placing the patient in a potentially life-threatening event caused by the cross-reaction between two drugs. Regarding claim 31, it would have been obvious to one having an ordinary skill in the art to modify Brown to employ in the health report to include a heath assessment summary because this raises patient awareness of a problem and therefore increase the chances that a patient will take an action to prevent the future problem diagnosed by the physician. This type of health assessment is well known in the art to be employed in patient health reports.

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### Allowable Subject Matter

Claims 32 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not fairly suggest or teach a test strip reader for reading a second type of test strip carrying a second sample of biological fluid and obtaining health related test results based on the second sample.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sam P. Siefke.

June 11, 2007